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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/940,283

Applicant(s)

BARDY ET AL.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-56,58-113,115,117-147,149 and 150 is/are pending in the application.
- 4a) Of the above claim(s) 3,47-51,60 and 108-112 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 113,115,117-132,134-147,149 and 150 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-31,37-46,52-56,58,59,61-92 and 98-107 is/are rejected.
- 7) ☒ Claim(s) 32-36,93-97 and 133 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/22/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 133 is objected to because of the following informalities: it is dependent on claim 133. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4, 16-18, 21, 23-25, 31, 39-40, 50, 52, 55-56, 59, 61, 64-69, 71, 75-80, 86, 92, and 100-101 are rejected under 35 U.S.C. 102(b) as being anticipated by Trabucco et al. (5,243,977).

Regarding claim 1, Trabucco shows an implantable cardiac device comprising a housing having a distal section and a proximal section, a top exterior surface, a proximal end and a distal end, wherein the top exterior surface along the distal section is contiguous with the top exterior surface along the proximal section, wherein the housing is substantially bilaterally symmetrical along a length of the housing's top exterior surface, wherein a width of the housing's top exterior surface at the distal section of the housing is less than a width of the top exterior surface at the proximal section of the housing, the width of the housing from the proximal section to the distal section; an electrical circuit located within the main housing section; and an electrode (905) electrically coupled to the electrical circuit and located on the distal housing section (Fig. 12).

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With respect to claim 52, Trabucco shows an implantable cardiac device comprising a main housing section having an exterior surface; a distal housing section extending distally from the main housing member, wherein the distal housing section has an exterior surface that is contiguous with the exterior surface of the main housing section and has a width less than the width of the main housing section; an electrical circuit located within the main housing section; and an electrode (905) electrically coupled to the electrical circuit and located on the distal housing section (Fig. 12).

Regarding claims 2, and 4, Trabucco shows at least a portion of the distal end and proximal end is rounded (Fig. 12).

With respect to claim 16, Trabucco shows the proximal end of the housing is contiguous with the distal end of the housing (Fig. 12).

Regarding claims 17-18, and 79-80, Trabucco shows at least a portion of the housing comprises an electrically nonconductive or insulated material (Col. 7 lines 29-31 (Fig. 12).

With respect to claims 21, and 84, Trabucco shows the housing comprises a polymeric material (Col. 6, lines 52-63)

With respect to claim 23, Trabucco shows at least a portion of the electrode is non planar (rounded ends) (Fig.12).

Regarding claim 24, Trabucco shows the housing is substantially planar (top and bottom as shown in profile in Fig.12).

With respect to claims 21, and 84, Trabucco shows the housing comprises a polymeric material (Col. 6, lines 52-63)

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Regarding claims 25, 31, 86, and 92, the statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. The electrical circuit could provide cardioversion-defibrillation and the electrode of Trabucco could emit energy for shocking the patient's heart.

With respect to claims 39-40, and 100-101, Trabucco shows at least a portion of the electrode (905) is non planar and circular in shape (Fig.12).

Regarding claim 55, Trabucco shows the implantable cardioverter is substantially bilaterally symmetrical along the length (Fig. 12).

With respect to claim 56, Trabucco shows the distal housing section is in fluid communication with the main housing section (Fig.12).

Regarding claim 59, Trabucco shows the distal housing section has a distal end section and at least a portion of the distal end of the distal housing section is curved (Fig.12).

With respect to claim 61, Trabucco shows the main housing section has a proximal end and at least a portion of the proximal end of the main housing section is curved (Fig.12).

Regarding claims 64-69, Trabucco shows the distal housing section comprises a shoulder region extending distally from the main housing section having a width less than the width of the main housing section, and the width of the shoulder region decreases proportionally as the shoulder region extends distally from the main housing section, and comprising a distal head extending distally from the sholder region and defining the distal end of the distal housing section and having a width that is less than the width of the shoulder region (Fig 12).

Regarding claim 71, Trabucco shows the depth of the distal housing section is less than the depth of the main housing section (Fig.12).

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With respect to claims 75-77, Trabucco shows at least a portion of the distal housing section and at least a portion of the main housing section is substantially non planar and at least a portion of the main housing section is substantially planar (Fig. 12).

Regarding claim 78, Trabucco shows the distal housing section is substantially bilaterally symmetrical along its length (Fig. 12)

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco et al. (5,243,977). Trabucco discloses the claimed invention except for the specific dimensions of the housing. It would have been an obvious matter of design choice to form the width of the proximal end and the distal end of the housing to be from 1 cm to 10 cm wide or 2 cm to 5cm wide, the depth of the proximal end of the housing to be less than 15 mm, the depth of the distal end of the housing to be approximately 1 mm to 15 mm or 1 mm to 3 mm, and the length of the housing is approximately 3 cm to 30 cm long, or 5 cm to 20 cm long since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

6. Claims 15 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco et al. (5,243,977) in view of Meltzer (5,645,586). Trabucco is as explained before.

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Trabucco discloses the claimed invention except for the proximal end of the housing being hinged to the distal end of the housing, or the main housing section hinged to the distal housing section. Meltzer teaches a housing having hinges between sections of the housing, where the hinges provide the housing the ability to conform to and flex with the implantation site (Col. 2, lines 17-30). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a hinge as Meltzer teaches between the proximal end and the distal end of the housing, or the main housing section hinged to the distal housing section of Trabucco in order to for the housing the ability to conform to the implantation site and flex with the implantation site.

7. Claims 19 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco et al. (5,243,977) and further in view of Hassler et al. (5,470,345). Trabucco is as explained before. Although Trabucco fails to teach the housing or the main housing section comprises a ceramic material, attention is directed to Hassler et al., which teaches forming implantable medical devices from ceramic. Hassler teaches that the use of ceramics for the implantable medical device enclosure makes the enclosure transparent to RF waves for telemetry purposes. Hassler further teaches that metal enclosures often cause interference during telemetry (Col. 1, lines 19-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to form the housing or main housing section of Trabucco to comprise ceramic material as Hassler teaches in order to make the enclosure transparent to RF waves for telemetry purposes.

8. Claims 20-22, 82, and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco (5,243,977) and further in view of Kenny (3,842,842). Trabucco is as explained

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before. Although Trabucco fails to teach the housing or main housing member comprises a titanium alloy or a polymeric material of silicone, attention is directed to Kenny which teaches a metallized surface of titanium alloy on a pacemaker to reduce the effects of electrical interference signals on the functioning of the circuit and a silicone coating over the metallized surface to protect the metallized surface (Col. 1, line 66-Col. 2, line 19). Therefore, it would have obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Trabucco to include a housing or main housing member comprising a titanium alloy or a polymeric material of silicone as Kenny teaches in order to reduce the effects of electrical interference signals on the functioning of the circuit and to protect the metallized surface.

9. Claims 26-28, 30, 87-89, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco et al. (5,243,977) in view of Mower (5,871,506). Trabucco discloses the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic (i.e. multiphasic) waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Mower also teaches that application of monophasic pacing pulses is well known, though it doesn't have the advantages of biphasic pacing pulses (Col. 6, line 23 – Col. 7, line 60). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply monophasic, biphasic (i.e. multiphasic) pacing pulses as Mower teaches with the device of Trabucco since they are well known in the art and the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.



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10. Claims 27, 29, 88, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco et al. (5,243,977) in view of Whigham et al. (4,821,724). Trabucco discloses the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing.

Whigham et al. teaches the application of triphasic (i.e. multiphasic) pacing pulses so that reliable sensing of evoked responses can be sensed (Col. 2, line 63-Col. 3, line 1) due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse (Abs).

Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply triphasic pacing pulses as Whigham et al. teaches with the device of Trabucco since the application of triphasic pacing pulses enables reliable sensing of evoked responses due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse.

11. Claims 37-38, and 98-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco (5,243,977). Trabucco is as explained before. Although Trabucco fails to teach the electrode can receive sensory information, it is well known in the art to utilize electrodes that can both stimulate and sense in order to reduce the number of electrodes needed and the required conductors. Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the electrode of Trabucco to be able to receive sensory information since it is well known in the art to provide electrodes capable of both stimulation and sensing.

12. Claims 41-46, and 102-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco et al. (5,243,977). Trabucco is as explained before. Trabucco discloses the claimed invention except for electrode being circular, ellipsoidal, square, rectangular, triangular,

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thumbnail or spade shaped. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the shape of the electrode as taught by Trabucco with a ellipsoidal, square, rectangular, triangular, thumbnail or spade shaped electrode, since applicant has not disclosed that a ellipsoidal, square, rectangular, triangular, thumbnail or spade shaped electrode provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any shape electrode such as the rectangular electrode taught by Trabucco for applying defibrillation energy.

13. Claims 53-54, 62-63, and 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco et al. (5,243,977). Trabucco discloses the claimed invention except for the specific dimensions of ICD. It would have been an obvious matter of design choice to form the width of the main housing section to be from 3 cm to 30 cm wide or 3 cm to 20cm wide, the depth of the distal housing section to be less than 15 mm, the depth of the main housing section to be approximately 1 mm to 15 mm or 1 mm to 10 mm, and the length of the housing is approximately 5 cm to 20 cm long or less than 30 cm long since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

14. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco (5,243,977). Trabucco discloses the claimed invention except for the distal head of the distal housing section having a width that is greater than the width of the shoulder region of the distal housing section. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the distal head, the shoulder region and distal

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housing section as taught by Trabucco the distal head of the distal housing section having a width that is greater than the width of the shoulder region of the distal housing section, since applicant has not disclosed that this particular shape provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any shape of the distal head, the shoulder region and distal housing section such as the distal head, the shoulder region and distal housing section taught by Trabucco for providing an implantable device housing. A change in shape absent persuasive evidence of the significance of the configuration has been held to be a matter of obvious design choice to one with ordinary skill in the art. See *In re Dailey*, 357 F.2d 669 (CCPA 1966).

15. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco (5,243,977). Trabucco is as explained before. Although Trabucco fails to teach the main housing member comprises stainless steel, it is well known in the art to utilize stainless steel for an implantable device housing. See Greatbach (4,157,720), and Bilitch (4,256,115). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Trabucco to include a main housing member comprising stainless steel since it is well known in the art to utilize stainless steel for an implantable device housing.

***Allowable Subject Matter***

16. Claims 113, 115, 117-132, 134-147, and 149-150 are allowed.

17. Claim 133 would be allowable if rewritten to overcome the objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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18. Claims 32-36, and 93-97 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to teach or suggest an implantable cardiac device comprising a housing having a distal section and a proximal section, a top exterior surface, a proximal end and a distal end, wherein the top exterior surface along the distal section is contiguous with the top exterior surface along the proximal section, wherein the housing is substantially bilaterally symmetrical along a length of the housing's top exterior surface, wherein a width of the housing's top exterior surface at the distal section of the housing is less than a width of the top exterior surface at the proximal section of the housing, the width of the housing from the proximal section to the distal section; an electrical circuit located within the main housing section; and an electrode electrically coupled to the electrical circuit and located on the distal housing section that can emit an energy for shocking the patient's heart between approximately 50J and 75J; 75J and 100J; 100J and 125J; 125J and 150J; and approximately 150J. Trabucco shows a cardiac stimulation device of the claimed shape and having an electrode, however there is no teaching or suggestion to provide energy of such great magnitude with the electrode. Applying energy within the claimed ranges with the electrode of Trabucco would most likely cause severe damage to the heart due to the small size of the electrode.

### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Turcott (6,409,675) shows a implantable device housing of the claimed shape in Figs. 3a-3c.

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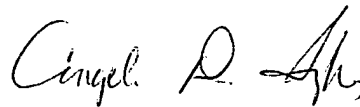
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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